REMARKS

Claims 34 to 38 remain in the application and stand rejected. Applicants note appreciably that the rejections partially based on references Bierman et al and Raulerson have been withdrawn.

Claim 34 is amended to overcome the rejection thereof under Section 112, second paragraph. Claim 34 is additionally amended to clarify that the site selectable by the practitioner is along the first and second proximal end regions.

Claims 34 to 37 stand rejected under 35 USC 103(a) as being unpatentable over Ash et al (U.S. Patent No. 5,947,953) in view of Markel et al (U.S. Patent No. 5,624,413) or Martin (U.S. Patent No. 4,682,978). Claim 38 stands rejected under 35 USC §103(a) as being unpatentable over Ash et al in view of Markel et al or Martin and further in view of Cazal (U.S. Patent No. 5,800,414). Claims 34 to 38 also stand rejected under "nonstatutory obviousness-type double patenting" in view of Serial No. 10/974,267.

In the presently claimed invention, the hub member is easily releasably securable to the catheters by snap fit around continuing lengths of the proximal portions of the catheter so that the proximal catheter ends extend beyond the hub proximal end for attachment to fittings and, preferably, extension tubes. This invention provides the capability of retrograde tunneling of a catheter assembly, that is, tunneling of the proximal end of the catheter after insertion of its distal end into the vasculature and after optimal locating of the catheter's distal tip, since no structure is affixed to the catheter proximal end prior to tunneling. Importantly, the hub's site along the catheter is optimally selectable by the practitioner after catheter implantation and subcutaneous tunneling of the catheter proximal end portions, who may have to trim the length of the catheter tubes rather than rely on an immediately available extensive inventory of short catheter lengths needed to address needs of different patients. This Y junction hub manages the extracorporeal catheter portions by securing together the proximal lumen portions, and also protects the tunnel exit site against any further undesirable splitting apart of the proximal lumen portions. Further, the hub member is releasable from the catheter should it become necessary to repair the catheter: the present invention also provides for repair of catheters that have already been implanted into a patient, without removing a damaged catheter from the patient and re-implanting a new one, causing accompanying distress and risk to the patient. Reference is made to the Specification at paragraphs [0006] to [0008] and [0057] and [0059]. Thus, the presently claimed invention is a greatly advantageous breakthrough in catheter implantation and repair procedures.

References Ash et al and Cazal have been discussed and distinguished in previous responses.

Reference Markel et al sets forth a method of implanting two independent catheters side-by-side in a common vein and subcutaneously tunneled together, with improved final distal tip positioning whereafter they are anchored.

Reference Martin sets forth a dual lumen catheter, using a coupling member at the proximal end for separating the proximal openings to the respective lumens for connection thereto of respective extension tubes, as illustrated in Figures 12 to 13d, in order to strengthen the Y-joint coupling of the extension tubes to the catheter end. The coupling member is an eventually Y-shaped (originally cylindrical) connecting piece such as of heat-shrinkable material wrapped around the proximal catheter end, whereafter the proximal lumen openings (and the proximal portion of the connecting piece therearound) are conically enlarged by tooling for tapered distal ends of the extension tubes to be inserted thereinto and affixed with minimal disturbances of the smooth interior surfaces between the extension tube channels and the catheter lumens.

Regarding claim 34, the Office Action asserts that reference Ash et al discloses a hub member that is adapted to be releasably attachable to and around the first and second proximal end regions of the first and second catheters distally of the proximal ends thereof, after catheter implantation and subcutaneous tunneling and at a site selectable by the practitioner." Ash et al discloses in Figures 1 to 3 and 5 to 7 a hub member 24 already affixed to the catheters. The reference mentions hub 24 only at column 5, line 60 and discusses the hub only at column 11, line 60 to column 12, line 37. In order for a hub to be "adapted to be releasably attached" to a catheter, it must first be a separately existing component, and such a separately existing hub component is not disclosed by the reference. Figure 2 shows internal detail of the Y junction between the catheter lumen proximal ends and the respective extension tubes encased within a hub 24, with channels of the hub extending between the spaced apart ends of the catheter lumens and the extension tube distal ends. The only portion of reference Ash et al discussing the Y junction and hub 24 is column 12, lines 15 to 32, wherein it is clearly expressed that the catheter lumens terminate in the hub and the extension tubes begin within the hub; thus, the catheter lumens expressly do not extend completely through the hub beyond the proximal end of the hub. Since the hub is a part of the catheter assembly located at the proximal ends of the catheters, the site of the hub along the catheters is not selectable by the practitioner. In fact, the artisan clearly

understands that, conventionally, hubs become part of catheter assemblies at the factory by being insert molded to the catheter proximal ends and extension tube distal ends at the factory to assure sealing as well as assured fluid communication between the extension tubes and the catheter lumens. Consequently, the embodiment of Ash et al having a hub (Figures 1, 1a, 2 and 5 to 7) is not of a catheter assembly capable of retrograde tunneling.

While reference Ash et al also expresses that a catheter assembly need not have any hub at all (column 12, lines 3 to 14), the reference does not express that a hub component may be added by the practitioner at a site selected by the practitioner.

Regarding the Office Action reliance on *In re Hutchison* and *In re Pearson*, reference is made to *In re Venezia*, 530 F.2d 956, 959 (CCPA, 1976), wherein the Court acknowledged that "adapted to be affixed" language can be a valid claim limitation because it has structural implications. Applicants traverse the characterization of the reference by the Office Action and the Office Action's refusal to acknowledge a meaning to the "adapted" limitation in claim 34.

The Office Action asserts that reference Markel et al discloses a hub member by referring to component 90 in Figs. 6 and 7. Component 90 is not a hub equivalent to the **multiple catheter** hub of the present claim, since it is not attached to two catheter lumens distally of their proximal ends, and it is simply a covering (or fitting) affixed to a proximal end of a single one-lumen catheter to detachably couple it to a distal end of a single associated extension tube assembly 76 having a mating fitting affixed thereon. Applicants respectfully traverse the combination of reference Markel et al with reference Ash et al.

The Office Action refers to connecting piece 28 of reference Martin affixed at the proximal ends of the two lumens of the dual lumen catheter, for strengthening the coupling to distal ends of respective extension tubes in a Y junction arrangement. The Office Action does acknowledge that the connecting piece is positioned **at** the proximal catheter lumen ends and that the proximal catheter portions do not extend beyond the proximal end of the connecting piece, but the Office Action asserts that it is an "equivalent structure essential working parts of a device that involves only routine skill in the art." Thus the Office Action admits that even combining reference Martin with reference Ash et al does not result in meeting the limitations of the present claims. Applicants traverse the assertion of the Office Action with respect to the arrangement of Martin being an "obvious" equivalent to the claimed invention: the Office Action fails to provide a clear line of reasoning with rational underpinnings. The connecting piece of Martin is only sensible at the

connection of catheter lumen proximal ends with extension tube distal ends, a site that is not selectable by a practioner; furthermore, the coupling member of Martin is disclosed to be affixed at the factory, because of the reference to mandrels and heat shrink material, not known to be available at a patient's bedside where the practitioner implants and tunnels a catheter. Not only has the Examiner failed to provide a clear line of reasoning for combining a part or bit of reference Martin with reference Ash et al, the Examiner has failed to establish a prima facie case of obviousness, and Applicants respectfully traverse the assertion concerning Martin and its combination with reference Ash et al. No reference, nor any combination thereof, meets the claim limitation that the hub member is: 1) releasably attachable to 2) portions of the catheter lumens distally of the proximal ends thereof, and Applicants respectfully traverse the rejection.

Claims 35 to 37 depend from claim 34, which is believed to patentably distinguish over the reference, and therefore, claims 35 to 37 are believed patentable.

With respect to the rejection of claim 38 over Ash et al in view of Markel et al or Martin and Cazal, Cazal does not teach adhesive to be splittable but instead expressly teaches that a drop of adhesive be placed at the end of already split proximal ends to prevent further splitting. Applicants continue to traverse the rejection. If the adhesive **stops** splitting apart of catheters, the adhesive cannot properly be said to join together two catheters in a manner whereby they are then splittable. Additionally, claim 38 depends from claim 34, which is believed to be patentable.

Claims 34 to 38 stand rejected for "nonstatutory obviousness-type double patenting" in view of the claims of pending but later-filed continuation-in-part application Serial No. 10/974,267. The present rejection is only provisional, since the present application has a filing date earlier than the other application and once all other rejections of the present claims is overcome, the double patenting is required to be withdrawn and the present application issue. Applicants traverse the assertion in the Office Action that the claims of the other application which do not include a hub limitation, cover the present claims of a hub adapted to be releasably attachable to portions of catheter lumens distal of their proximal ends.

The claims are believed to distinguish patentably over the prior art, and allowance thereof is respectfully urged. No new limitations have been entered into the claims, and no new issues are raised. No new matter has been entered hereby. If any additional fees are due, please charge same to Deposit Account No. 50-2434.

Respectfully Submitted,

J. Daniel Raulerson et al

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/Anton P. Ness/

By: Anton P. Ness
Reg. No. 28,453
Fox Rothschild LLP
10 Sentry Parkway, Suite 200
P.O. Box 3001
Blue Bell, PA 19422-3001
Telephone: 610-397-7984
Facsimile: 610-397-0450
E-Mail: ipdocket@foxrothschild.com
Customer No. 33941